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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,981	08/03/2006	Hansgeorg Schaaf	102435.57668US	7084

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EXAMINER	
NGUYEN, TINA MY PHUONG	
ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,981	SCHAAF, HANSGEORG	
	Examiner	Art Unit	
	TINA NGUYEN	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/03/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 08/03/2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to in foreign reference DE2011886U1 has not been considered.

Specification

2. The disclosure is objected to because of the following informalities:

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

4. It is suggested that applicant use the headings above, where relevant, to separate the application into different sections and identify which sections correlate to which headings.

5. The number "2" should be changed to –20—on page 8, line 9. The number "18" should be changed to --13-- on page 8, line 28. Furthermore, there are numerous instances on page 11 in which the reference numbers used for parts are inconsistent with the numbers previously assigned to those parts.

6. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim **1** is rejected under 102(a) as being anticipated by McWeeney et al. (U.S. Patent Pub. 2005/0272975). McWeeney et al. disclose **an endoscope comprising a**

flexible catheter probe (Fig. 9) **having a plurality of lumens** Figs. 2-4), **a handle** (1130A, Fig. 11) **provided at the proximal end of the probe, an optical system** (940, paragraph [0114]) **provided in at least one optical system lumen of the catheter probe, at least one working lumen** (60, Fig. 3) **for a surgical instrument and a control element** (968, Fig. 9, paragraph [0114]) **which is fixed to the distal end of the probe or in the proximity thereof for bending the end of the probe and is guided movably in the axial direction at the probe** (where it is inherent that the control element must be fixed to the distal end in order to be able to actuate steering of the catheter), **characterized in that the optical system which projects beyond the proximal end of the catheter probe** (Fig. 9) **is guided movably in a flexible tube** (24, paragraphs [0103] and [0114], wherein if the optical system is insertable in the catheter, it is guided movably even when it is in the tube) **; the tube is elastically resilient in its longitudinal direction and is fixedly connected at a fixing location to the optical system** (wherein it is inherent that the optical system and tube is fixedly connected to each other)**; and the distal end of the optical system is pressed by the tube against a translucent cover** (22, paragraph [0103]) **which closes the distal end of the optical system lumen.**

9. Claims **1-5, 11-12, 17-19** are rejected under 35 U.S.C. 102(b) as being anticipated by Ebling et al. (U.S. Patent 5,569,161).

10. As to claim **1,** Ebling et al. disclose **an endoscope comprising a flexible catheter probe** (Fig. 1) **having a plurality of lumens** (30, 44, Fig. 4C, Col. 6, lines 14-16), **a handle** (28, Fig. 1) **provided at the proximal end of the probe** (where 26 is

located), **an optical system** (14, Fig. 2) **provided in at least one optical system lumen of the catheter probe** (wherein it can be seen in Fig. 4C that optical system 14 has its own lumen in the probe), **at least one working lumen** (30) **for a surgical instrument and a control element** (Col. 7, lines 57-60) **which is fixed to the distal end of the probe or in the proximity thereof for bending the end of the probe and is guided movably in the axial direction at the probe** (where it is inherent that a steering means, considered to be a control element, will have to be fixed to the distal end), **characterized in that the optical system which projects beyond the proximal end of the catheter probe** (14, Fig. 2, Col. 5, lines 59-62) **is guided movably in a flexible tube** (24, Col. 6, lines 41-43) **; the tube is elastically resilient in its longitudinal direction and is fixedly connected at a fixing location to the optical system** (Col. 9, lines 40-44, also the optical system and tube must be connected to each other at point 22, Fig. 1)**; and the distal end of the optical system is pressed by the tube against a translucent cover** (38, Fig. 4A, Col. 6, lines 38-44) **which closes the distal end of the optical system lumen.**

11. As to claim **2,** Ebling et al. disclose that the fixing location is provided at the proximal end of the tube (Fig. 1).

12. As to claim **3,** Ebling et al. disclose that at the proximal end of the optical system is a connecting portion (10) which is connectable to an illumination device and/or to an ocular (Col. 5, lines 50-53).

13. As to claim **4,** Ebling et al. disclose that the fixing location (22) is provided at the connecting portion (Figs. 1&2)

14. As to claim **5,** Ebling et al. disclose that the flexible tube is arranged outside the handle (Fig. 1).

15. As to claim **11,** Ebling et al. disclose that the catheter has a balloon (54, Fig. 8) to which a dilation medium can be fed by way of a balloon lumen in the catheter probe.

16. As to claim **12,** Ebling et al.'s discloses a lumen which extends from the distal end of the probe to an exit opening in the catheter which is behind the balloon (wherein the lumen is the working channel 30 and the lumen opening is the working channel opening, 36, Fig. 1). This lumen is capable of guiding a guide wire.

17. As to claim **17,** Ebling et al. disclose that the surgical implement is removable from the at least one working lumen or is incorporated or integrated into the catheter probe (Col. 6, lines 18-20, wherein the "utensils" are the surgical implements and because they can be inserted, they can also be removed from the lumen).

18. As to claim **18**, Ebling et al. disclose that the catheter probe is in the form of a disposable component for any material is inherently capable of being disposed.

19. As to claim **19,** Ebling et al. disclose that the catheter probe is an injection molded component or an extruded component (Col. 5, lines 66-67).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims **6-10, 13-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebling et al. (U.S. Patent 5,569,161) as applied to claim 1 above, in view of Shockey (U.S. Patent 5,168,864).

22. As to claim **6,** Ebling et al. do not disclose that the catheter probe is mounted rotatably to the handle in a rotary bearing through which the control element is displaceably guided. However, in Ebling et al. 's device, access to the optical system (14) and working channel (30) are acquired at different places on the catheter (one at 36, the other at 22, Fig. 2).

23. Shockey discloses a deflectable endoscope (10, Fig. 1) in which the deflecting motion is actuated by a pull wire (24) supported by a stainless steel tube (20). The tube extends from a more distal portion of the endoscope to the handle 12 of the endoscope and is attached there by a Touhy-Borst type clamp 21 and when "released is axially rotatabe 360 degrees" (Col. 3, lines 63-65). Because the tube is a part of the endoscope, it is considered that the endoscope is mounted rotatably to the handle. Endoscope designs are known in the art to be applicable to catheter designs. Therefore, it would have been obvious to impart Shockey's deflecting mechanism and handle assembly to Ebling et al.'s working channel access point in order to give the device a deflecting mechanism that will allow the operator to steer the probe.

24. As to claim **7,** Shockey discloses that a releasable fixing device is provided on the rotary bearing (wherein when the Touhy-Borst type clamp is released, it allows the free movement of the tube 20 and when it is closed, it fixes tube 20).

25. As to claim **8**, Shockey discloses that the rotary bearing has a manually actuable rotary portion which is non-rotatably connected to the catheter probe (wherein the clamp 21, along with the entire endoscope, can be rotated manually, i.e. by hand, while the clamp is in a closed position, preventing the rotation of the clamp separately from the tube 20).

26. As to claim **9,** Shockey discloses that the control element (24, Fig. 1) is passed through the fixing device.

27. As to claim **10,** Shockey discloses that the proximal end of the control element is passed through the fixing device (Fig. 1).

28. As to claim **13,** Shockey discloses that the control element (24, Fig. 1) is arranged in a flexible support tube (20) which is arranged in a control lumen of the catheter probe and terminates at a given spacing (D1) from the distal end of the probe, wherein the given spacing corresponds approximately to the length of the distal portion of the probe, which is to be bent over by the control element (Fig. 3, Col. 3, lines 62-63).

29. As to claim **14,** Shockey discloses that the control element is fixed to the distal end of the catheter probe by a shrink tube or by an adhesive (28, Fig. 1, Col. 4, lines 7-8).

30. As to claim **15,** Shockey discloses that the support tube is fixed at a fixing location in the axial direction (wherein the tube is fixed at point 21, Fig. 1, when the clamp is closed). The remaining portion of the support tube is considered to be movable with respect to the inside wall of the control lumen because the support tube is not fixedly attached to the control lumen.

31. As to claim **16**, Shockey discloses, in another embodiment, that there are two tubes that offer support to the control element. Tube 64 is axially movable, controlled by clamp 68, and tube 60, which is fixedly received within the lumen 63 (Col. 5, lines 13-16). In order to be fixedly received, the tube has to be fixed at some fixing location. Although Shockey is silent as to the exact fixing location of the first tube, one of ordinary skill in the art would appreciate that in order for the proper functioning of the invention, the tube would just need to be fixed at a location and the exact location of the fixing does not matter. Therefore, it would have been obvious to one of ordinary skill in the art to fix the tube at the distal end of the support tube and still arrive at the same predictable endoscope.

Conclusion

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Barthel et al. (U.S. Patent 5,921,917) discloses a flexible optical system that encased by a flexible tube.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TINA NGUYEN whose telephone number is (571)270-1489. The examiner can normally be reached on M-Thurs 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739

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8/18/2009